Mexico, D.F. April 3rd, 2003.

Dockets and Management Branch (HFA 305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0276; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Federal Register 5377 (February 3, 2003)

The National Agricultural Council (NAC) is conformed by near 150 Members; it's partners are Agricultural and Cattle Producer's Organizations of Mexico.

As associates has Farm Services Suppliers Organizations and Agricultural and Livestock industry enterprises, who enforces and compliment sectorial activities. Our organism is the most important at national level; it's members contribute with 70% of Gross Domestic Agricultural Product, 85% of Gross Domestic Livestock, 70% of Gross Domestic Agricultural Industry related Products and 75% of Total Agricultural Exports.

The NAC strongly believes that enhanced security of the U.S. food supply is crucial for the continued safety of U.S. consumers and their confidence in the food imports.

Attach to this letter we send comments about the Bioterrorism Act 's Title III section 305, received for some of our members.

The NAC wishes to reiterate that we fully support measures to ensure that we can deliver food safe, secure produce to American consumers. However, we do not feel that the current prior notice proposal will be an effective mechanism to accomplish the desired objectives of the FDA.

Our members stands ready to work with the FDA in implementing a system that would fully take advantage of existing resources and in sharing our first hand knowledge of current exporting procedures to help the FDA to develop an efficient system that could enhance security of the U.S. Food supply system.

Sincerely,

Armando Paredes Arroyo Loza
President

Alfredo Moises Ceja
Vicepresident, Foreign Trade

02N-0276 C91

Comments of the National Agricultural Council about
The Bioterrorism Act

I.- General Comments for the Food and Drug Administration (FDA) Authority

1.1. The United States Government has the right to establish its own laws; however we appeal for this Law to give us as country a **Most Favored Nation** treatment, far from becoming a non tariff barrier for the Mexican exports, and to comply with the **North American Free Trade Agreement (NAFTA)** rules.

1.2. This Law enforcement **must not result** in a **slower** customs inspection process that could delay the delivery of merchandise, consequently affecting the **perishable products quality**, the **timeliness of its delivery**, the **shelf life** required by the buying companies, and it could become a **non tariff barrier to trade** that may transgress NAFTA provisions and World Trade Organization (WTO) agreements.

1.3. Provided that there is an **agri-food products export tradition** from Mexico to the U.S. under NAFTA, we propose to set up a **cooperation outline** between both countries **to ease** the compliance of this Law provisions. This could be particularly applied to companies who have a good record of integrity and fulfillment similar to that of the **Business Anti-Smuggling Coalition (BASC) Program**.

1.4. We propose the **source inspection**, and in fact there are operating verification programs at source currently working, for **fresh fruits and vegetables** exports for them to comply with U.S. phytosanitary regulations, and which are 100% inspected in their production, packing, certification and export processes by **USDA employees**. We consider the FDA can make use of this operating system.

1.5. About the **confidentiality of the information** contained in the facilities registration and provided by the companies, there must be a guarantee that it must be **strictly** kept that way, avoiding risks of exposure in handling this information.

1.6. There must also be provided guarantees of the **sustainability and effectiveness** of the computerized system to avoid delays and unintentional faults about regulations.

II.- Particular Comments for the Food and Drug Administration (FDA) Authority

2.1. Fruits Producer and Exporters

2.1.1 EMEX[1/] point of view

Section 305 Title III Facilities Registration

- ✓ Our association has all of its members registered in the USDA. As EMEX, we believe that the same registration can be transferred to the FDA to avoid the duplication of efforts.

2.2.2. Unión Agricola Estatal de Michoacán[1/]

- ✓ We do not agree with the application of unilateral measure in our country; we think that this might be a violation to the subscribed agreements of NAFTA for those countries who have signed this document.

- ✓ If this measure is taken without the agreement of our members, we propose that the mexican goverment should be tasked with the creation of the required mechanism for this regulation. We also consider that the implementations of these measures are a potential barrier and moreover for the comercial flow of our products.

- ✓ Our members and other export companies would like to ask for an extension of the period that you have suggested and also we would like to ask that the dissemination and training costs of these new regulations could be shared for all the people involved in the production and consumption chain.

- ✓ These regulations will affect our business, but specially they are going to discourage mexican exportations and agricultural business to the U.S.

2.2. Grupo Bimbo

These comments are submitted on behalf of Grupo Bimbo (GB), a company with assets in the USA such as Bimbo Bakeries USA. Our company is one of the leading baking companies in the American Continent, with operations in the U.S., Mexico, Central America, Peru, Colombia, Venezuela, Chile, Brasil, Argentina and Europe.

[1/] Emex = Packers of Mangoes for Export
[1/] Unión Agrícola Estatal de Michoacán = Michoacan State Agricultural Union

Section 305 Title III Facilities Registration

- ✓ The purpose of these comments is to voice our strong concern to the several parts of the agency's recent registration of food facilities proposal.

- ✓ While GB appreciates the efforts FDA has put forth in trying to develop a comprehensive and thorough approach to this registration, none the less, this proposal clearly might represent a paperwork burden and costs and it can be very damaging to the businesses of many bakers and their suppliers alike. We are questioning whether this proposal serves as an appropriate means to the stated goal and whether costs associated with such a proposal are outweighed by their usefulness in accomplishing the objectives of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

- ✓ GB understands that FDA's top priority must be to insure proper focus on the security of goods imported into the United States so that consumers can be assured of a wholesome and safe food supply. GB is hopeful that its comments will assist the agency as it moves forward to finalize this important policy.

Streamlining Registration

- ✓ We believe that it's important to establish a flexible definition of "entity" to allow companies to register as best suits their corporate structure. This would provide for the inclusion of one parent corporation to register all of its subsidiaries and plants through a single registration. This centralized approach would assist both the agency and companies to quickly and effectively pinpoint facilities in question.

- ✓ Through this streamlined approach, the parent company could electronically submit to FDA a list of its facilities that fall within the definition in Section 305 of the Bioterrorism Act and the new section to the Food Drug and Cosmetics Act, Section 415. Since the parent company currently maintains internal files that encompass all pertinent information regarding its subsidiaries and all of its facilities, in times of crisis, FDA could contact the parent company that could then take the appropriate actions for the facilities in question. Further, this would limit the contact names for a company which would streamline effective communication.

Clarification Needed on Proposal Terms

- ✓ GB requests that in its final rule, FDA more specifically define and give guidance on the definition of product categories for the purpose of category registration. 21 CFR 170.3(n) provides definition for general product categories, but does not clearly define which category certain grain based products such as snack cakes, sandwich crackers and cereal bars would fall under for filing purposes.
- ✓ Additionally, GB is concerned that FDA's applicability of the registration proposal to manufacturers of food contact materials, beyond those facilities that manufacture products for consumption, overreaches FDA's exercise of

enforcement discretion. GB estimates that this additional group of potential registrants would at the least quadruple the number of facilities that would need to register and would saddle the already burdened registration field with tens of thousands of additional records creating an unmanageable data base.

Insuring proper use of the information submitted

- ✓ GB is concerned that the Bioterrorism Act directed that registration information not be subject to disclosure under the Freedom of Information Act (FOIA). However, in FDA's proposal, the agency stated that it will share the filed registration information with other government agencies, provided that the other agencies give written assurance of the information's confidentiality. GB is concerned about the FOIA status of that sensitive information once it is in the hands of other agencies and of the possible disclosure of that registration information. FDA was not clear in its proposal why other agencies would be entitled to or need such information. GB believes further clarification is needed from FDA in this area.

- ✓ Since the FDA requests the registration, via internet, of the food facilities (domestic and foreign) that manufacture, process, package, receive or store food for human consumption, we would like to know what can guarantee that the forms are filled by the right individuals. The above is commented since we believe there might be apocryphal registration requests that could get an FDA number, and give the name and data of ghost companies or give the name of actual companies with erroneous information. These could be subscribed by third parties foreign to the real registered company.

- ✓ It would be necessary to implement some form of an access control system to the Registration operations, data update, as well as removal, in this manner, the ill use by third parties that could have access to the Registration procedure via Internet proposed by FDA, would be prevented.

Other Concerns

Email Addresses

- ✓ GB notes that the requirement of an email address as part of the required registration information may be an undue burden on small businesses in Mexico that may not have access to such technology. Additionally, language regarding email addresses is not consistent throughout the proposal. In some places the use of email is optional, while on the registration form, the email address is required.

- ✓ GB believes that this language needs to be clarified in the final rule.

Electronic Registration Form Processing

- ✓ FDA should pay special attention as to how the electronic registration form will allow registrants to proceed through the process.

- ✓ FDA should mark optional fields in some form such as an asterisk and program the electronic downloadable file to allow the registration to proceed as long as the mandatory fields have been completed. Another option would be for FDA to consider a second form for voluntary information to streamline the process and avoid registrant confusion between mandatory/optional information.

- ✓ We also find the Registration Form somewhat limited regarding space to consider for data of the companies that we must register, and it is proposed it accepts appendixes.

Registration Processing Dates

- ✓ To the degree possible, GB believes that FDA needs to embrace a more aggressive schedule for registration to begin before the proposed October 12, 2003 to ensure a smooth, effective registration process for all parties involved. If the dates for registration are not expanded, it is likely that FDA's computer registration system will become overburdened with so many companies trying to register within such a small time frame, that the task cannot be accomplished.

- ✓ Additionally, FDA should take into account that industry will need time to disseminate details to their suppliers and determine which facilities will be included in the required registration.

Estimate of Changes in Facility Registrations Per Year

- ✓ GB notes that FDA's proposal estimates a registration change in only 10% of facilities per year. We believes that this has been underestimated. If the proposal moves forward as it is currently drafted, almost all facilities would be making various changes throughout the year to update FDA on product category changes and personnel changes at facilities. The FDA should estimate the time and resources necessary throughout the year to keep the Agency updated.

- ✓ laws such as NAFTA and the WTO.

Nacional Agricultural Council

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For:	**Dockets and Management Branch (HFA 305)**
Organization:	**Food and Drug Administration**
From:	**Mr. Armando Paredes, President** **Nacional Agricultural Council**
Subject:	**Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**
Date:	**April 3rd, 2003**

Comments ___X____

To whom it may concern:

Attach to this fax cover we send comments about the Bioterrorism Act's Title III section 305 received for some of our members

Sincerely

Armando Paredes, President
Nacional Agricultural Council

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